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EXAMINER

KELLY, ROBERT M

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/849,664	Applicant(s) SZALAY ET AL.	
	Examiner Robert M. Kelly	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/19/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/26/04; 2/17/05; 8/4/05; 4/6/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response to restriction requirement and amendment of 4/4/06 is entered.

Claims 1-32 have been cancelled.

Claims 33-79 are newly added and presently pending.

Election/Restrictions

Applicant's election of Group I, drawn to treatment/diagnosis/visualization of a wounded/inflamed tissue or a disease associated therewith, comprising the administration of bacterial cells containing a DNA encoding a detectable protein, in the reply filed on 4/4/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant has cancelled all claims, and presents no new claims, drawn to non-elected inventions.

Hence, Claims 33-79 are presently considered with respect to the elected invention (bacterial cell) and species.

Drawings

Drawing 6 is objected to because the drawing has two panels, and according to the specification, the panels are labeled A and B, however, the panels are not labeled A and B, and therefore, it cannot be determined which panel indicates catheterized or non-catherized hearts (see specification, paragraph 0020).

Drawing 7 objected to because it is not clear which panel is heart, liver, or spleen, and further which panels are control or catheterized animals.

Claim Objections

Claims 61-63 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 61-63 add the further limitation that "detection is based on a signal"; however, all detections are based on some form of signal. Therefore, the claims fail to further limit their specific parent claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claims 33, 34, and/or 35 be found allowable, claims 61, 62, and/or 63, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in

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content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Specifically, claims 61-63 limit the detection mechanism of their respective parent claims to being based on a signal. However, all detections are based on signals. If there is no signal, there can be no detection. Hence, despite a slight difference in wording, the claims are substantial duplicates.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3-19 of copending Application No. 10/516,785. Although the conflicting claims are not identical, they are not patentably distinct

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from each other because Applicant's copending Application teaches broadly the cell/microorganism, and methods of diagnosis, and the specification of Application No. 10/516,785 is substantially identical to the present specification, describing the same uses, and while Application No. 10/516,785 may only broadly claim use, the specification then necessarily teaches the same invention claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 – new matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The pending claims encompass a detection method, in which bacterial cells are administered and detected, then a tissue commensurate with the scope is detected, and the only linkage between these steps is the fact that they occur in the same subject. However, the originally filed claims and specification provide explicit or implicit support for the step of detecting the bacteria, which indicates the tissue which meets the claims, and not for a separate

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detection of the tissue, after a non-linked administration and detection of the bacteria. Hence, Applicant's separate steps, without any nexus between the steps are new matter.

Furthermore, these claims encompass methods wherein the microorganism does not contain a DNA sequence encoding a protein capable of inducing a detectable signal, however the claims and specification as filed only provide implicit or explicit support for microorganisms containing such DNA sequence (e.g., claims 1 and 31). Hence, the claims comprise new matter for this aspect.

Claim Rejections - 35 USC § 112 – New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 38-39, 44, 47, 50, 53, 56, 63, 66, 73, 76, and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's claims encompass the diagnosis of low back pain, as well as herniated nucleus pulposis. However, Applicant's specification and claims as originally filed only provide support for low back pain which is herniated nucleus pulposis (e.g., paragraph 0046 and claim 21). Hence, the claims encompass new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35, 38-39, 44, 47, 50, 53, 56, 63, 66, 73, 76, and 79 are rejected under 35

U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's claims encompass the diagnosis of Crohn's disease, ulcerative colitis, atherosclerotic plaque, auto-immune disease, rheumatoid arthritis, multiple sclerosis, Alzheimer's disease, a fracture, an incision, and a burn. However, the specification and claims as originally-filed do not support these disorders for anything but treatment (e.g., paragraph 0046). Hence, the claims encompass new matter.

Response to Argument – new matter

Applicant's argument of 4/4/06 has been fully considered but is not found persuasive.

Applicant argues that new matter is not introduced, citing various locations in the specification (p. 6).

Such is not persuasive. The Examiner has considered each of the citations and not found any implicit or explicit support for the subject matter as claimed.

Claim Rejections - 35 USC § 112 – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's claims encompass pathogenic microorganisms, as well as microorganisms that are not recognized by the immune system. However, Applicant's specification specifically limits the use of the invention to non-pathogenic, and microorganisms recognized by the immune system (paragraph 0027). Hence, the Artisan would not reasonably determine Applicant to have possession of the invention as claimed.

Claim Rejections - 35 USC § 112 – Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The Law

In determining whether Applicant's claims are enabled, it must be found that one of skill in the art at the time of invention by Applicant would not have had to perform "undue experimentation" to make and/or use the invention claimed. Such a determination is not a simple factual consideration, but is a conclusion reached by weighing at least eight factors as set forth in In re Wands, 858 F.2d at 737, 8 USPQ.2d at 1404. Such factors are:

- (1) The breadth of the claims;
- (2) The nature of the invention;
- (3) The state of the art;
- (4) The level of one of ordinary skill in the art;
- (5) The level of predictability in the art;
- (6) The amount of direction and guidance provided by Applicant;
- (7) The existence of working examples; and
- (8) The quantity of experimentation needed to make and/or use the invention.

These factors will be analyzed, in turn, to demonstrate that one of ordinary skill in the art would have had to perform such experimentation as to amount to inventing Applicant's claimed subject matter for Applicant, and hence Applicant's claimed subject matter requires "undue experimentation" to make and/or use the invention, and that, therefore, Applicant's claims are not enabled.

The Level of Predictability in the Art

Because of the art, as shown above, does not disclose enough to reasonably predict the working embodiments encompassed by Applicant's claims, the Artisan could not predict, in the

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absence of proof to the contrary, that such applications would be efficacious in any diagnosis, as will be shown below.

Hence, absent a strong showing by Applicant, in the way of specific guidance and direction, and/or working examples demonstrating the same, such invention as claimed by Applicant is not enabled.

The Level of One of Ordinary Skill in the Art at the Time of Invention

The level of one of ordinary skill in the art at the time of invention was advanced, being that of a person holding a Ph.D. or an M.D.; however, because of the immaturity of the art, and its unpredictability, as shown by the other factors, one of skill in the art at the time of invention by Applicant would not have been able to make and/or use the invention claimed without undue experimentation.

The Breadth of the Claims

Applicant's independent claims are drawn to detecting the presence or absence of a wound/wounded tissue, inflammation site/tissue, or a disease/condition, in a subject (Claims 33-35, respectively). Each claim requires monitoring a subject to whom any detectable microorganism or cell has been administered, to detect the microorganism/cell, and then detecting the wound/tissue/inflammation/disease/condition, respectively, in the same subject. Dependent claims encompass microorganisms that are any bacteria, the condition being an atherosclerotic plaque, the cell being specifically retained at the wound/wounded tissue or inflammation site/inflamed tissue due to protection from the immune system and further being cleared without affecting normal tissues. Further dependent claims encompass any microorganism/cell which is capable of replication, intravenous administration, attenuated or

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non-pathogenic microorganisms, four genera and species of bacteria, the microorganism allowing for visualization and external visualization of the wounded/inflamed tissues, detection being based on a signal, signals of MRI, cells comprising a DNA encoding a contrast agent, chromophore, compound, or ligands for visualization, cells allowing detection via light, heterologous genes encoding fluorescent proteins, luminescent proteins, metal binding proteins, luciferase and/or its substrate, GFP or RFP.

The claims are broad for encompassing a wide variety of subjects, tissues, diseases, cells, microorganisms, and detection methods. The breadth encompassed requires a large amount of information to be provided by Applicant's specification and examples, and the Art at the time of filing, for the Artisan to reasonably predict the working embodiments encompassed by the breadth of the invention.

The Nature of the Invention

Applicant's invention is in the nature of detecting wounded tissues, inflamed tissues, or diseases/conditions, by the administration of any microorganism or cell and detecting their accumulation in the tissues affected (e.g., paragraph 0023). However, Applicant's claims appear to require separate detections of the microorganism or cell, and the tissue affected, and hence, there appears to be no direction and/or guidance for the presently claimed method. Hence, the Artisan would have to perform undue experimentation to determine the methods of detection, because the methods of detection would not reasonably be predictable.

The State of the Prior Art

Dr. Szalay's own article, Yu, et al. (2003) *Anal. Bioanal. Chem.*, 377: 964-72, provides a recent review of the Art, demonstrating that the Art is not generally enabling of the breadth of

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Applicant's invention. Specifically, Yu is directed to the administration of bacteria, viruses, or mammalian cells (BVMC) to subjects, which BVMC accumulates in cancerous tissues, and not any tissue of the claimed invention.

With regard to bacterial cells, Yu teaches a few species of bacteria which appear to preferentially colonize cancerous tissues, but the mechanism of such colonization, while proposed to be due to various things, is not yet elucidated (pp. 966-67). Moreover, a particular mouse was found that showed a very short term accumulation of bacteria which disappeared prior to full disappearance of the bacteria in a particular mouse strain (p. 966). Further, Yu discloses that administration-type-dependent colonization is common, but there appears to be no reasoning to predict which administration will yield which colonization type (p. 966, paragraph bridging columns).

The Direction and Guidance Provided by Applicant

Applicant's specification broadly discusses bacteremias and possible reasons why bacteria may colonize artificial materials in the body (pp. 1-3), a summary of the invention broadly discusses monitoring the colonization of bacteria in the body non-invasively, which is preferentially carried out with Applicant's Luxcdabe operon (pp. 3-4). Further broad description is provided stating that *S. typhimurium* disseminates through intravenous injection throughout the body, and may therefore reach the wounded/inflamed tissue by circulation (p. 6), broad description of the envisioned cell types, tissues, administrations, heterologous genes for therapy, discussion of luciferases, promoters, administrations, therapeutic use, and therapeutic proteins (pp. 7-14).

However, such broad description fails to provide the specific guidance and direction required to reasonably predict that any particular subject, tissues, diseases, cells, microorganisms, and detection methods, would be efficacious.

The Existence of Working Examples

Example 1 demonstrates the materials and methods used in the subsequent experiments. Example 2 demonstrates that distributions of bacteria into the body after administration are bacterial-strain dependent. Further, *V. cholera* appears to localized to the liver, within 5 minutes of injection, and remains visible in the liver at the one-hour period. The next experiment demonstrates that at 5 days, the cholera is cleared from the ear tag wound, and at 8 days, even the injection wound site is cleared of cholera. Next, it was demonstrated that in immunocompetent mice, ear tags were colonized four days after intravenous injection. Lastly, it was found that 24 of 29 injection wounds, and 12 of 29 ear tags were colonized by cholera. Example 3 demonstrates that *E coli* injected intravenously appear to colonize catheter-irritated hearts of rats, while those that are not so-irritated are unaffected, and the catheters are not affected.

The Amount of Experimentation to Practice the Invention

Applicant's examples and specification are not consistent, given the knowledge in the art, to the breadth of Applicant's claims. With regard to the microorganisms which may be administered, the Artisan would not reasonably predict that any microorganism would accumulate in any of the tissues claimed. To wit, for example, a bacteriophage cannot even infect eukaryotic cells, and hence would not be reasonably predicted to accumulate anywhere except the liver. Further, Applicant has stated in the specification that even the bacteria used to infect the rats used have distinct interactions with the host cell (paragraph 0061), and the

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distribution pattern of any particular bacteria is not reasonably predictable, being bacterial-strain dependent (paragraph 0060), and, moreover, the particular distribution patterns depends on the method of administration (paragraph 0045). Hence, any microorganism's exposure to any particular tissue, and its clearance, is not reasonably predictable. Given this, and given the number of microorganisms and cells and animals and forms of administration that are possible, the Artisan would have to perform undue experimentation to determine for each type of microorganism or cell, and each subject type, first, whether the administration yields the distribution which will yield positive results, and then determine when and where, by comparison to the non-affected subject, the colonization is different in the diagnosed subject. For example, by Applicant's method, if a rat was unaffected, accumulation in the liver would indicate that the liver had a wound, inflammation, and coronary artery disease. This simply is not the case, as it is the artifact of the nature distribution of the bacteria used. Further, given that the colonizations are not permanent and do not necessarily occur immediately, as shown in the Yu article, above, as well as Applicant disclosure (paragraph 0061), the Artisan would have to determine the distribution over time for a non-affected individual for comparison, prior to performing the method, and may still only expect the method to be accurate, at best, only 41.4% of the time (paragraph 0061). Applicant may argue that 82.8% of injection wounds also showed such colonization, but such may also be explained by the fact that such is where the bacteria was present in high concentrations, and hence, it would not be reasonably predictable for non-injection wounds, and therefore would require undue experimentation for the breadth to make it so-predictable.

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With regard to Applicant's detection methods, the specification only discloses fluorescent proteins, for detection by light emission, and by MRI, (e.g., p. 8). However, Applicant's claims encompass any detection method. However, given that Applicant wishes to detect these tissues, the method would not be one which causes any damage to the organism itself, because, according to the method, the microorganism/cell would accumulate in the damaged tissue, and provide false readings, it would appear that the only methods of detection are by MRI or fluorescence detection. However, particular chromophores/fluorophores would not be reasonably predicted to detect tissues deep in the animal, and would necessarily be limited to surface tissues of the animal, e.g., SPECIFICATION, p. 10.

Conclusion

Because of the undue experimentation required to reasonably predict the working embodiments, the claimed invention would require the Artisan to perform undue experimentation, and hence, the claims are not enabled.

The following rejections are made because of the breadth of the claims, even in light of the lack of enablement.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 33-34, 36-37, 42-43, 57-62, and 69-72 rejected under 35 U.S.C. 102(b) as being anticipated by Pace (2000) JAMA, 284(22): 2964.

With regard to Claims 33-34, Pace teaches that sore throats can be diagnosed to be caused by Streptococcus bacteria with a throat culture. Such patient typically presents with a

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sore throat and inflammation (wounded) tissue in the throat. The detection of the tissue is found by visual diagnosis of the throat, and the detection of the previously administered bacteria, by throat culture. Hence, Pace anticipates the claims.

With regard to claims 36-37 Streptococci are bacteria.

With regard to claims 42-43, Streptococci are known to replicate.

With regard to claims 57-60, the microorganism allows for visualization, which is external to the patient, by looking at the throat.

With regard to 61-62, the detection is visual in every case (both culture and viewing the throat).

With regard to 69-70, the detection is visual and hence, by light.

With regard to 71-72, it is well known that such microorganisms contain DNA encoding metabolic proteins which bind to metals, e.g., the electron transport system.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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